

REMARKS

Claims 1, 3-10, 19-23, and 27-36 are pending in the application. No claims have been added, amended, or cancelled. Accordingly, claims 1, 3-10, 19-23, and 27-36 remain pending and under examination. Applicants respectfully request reconsideration and allowance of the claims in view of the remarks provided herein.

Claim Rejections - 35 USC §103(a)

The Examiner has rejected claims 1, 3-10, 19-23, and 27-36 under 35 U.S.C. 103(a) as being unpatentable over Killion (U.S. Patent No. 6,022,371) in view of Lafont *et al.* (U.S. Patent No. 5,957,975). Applicants respectfully traverse the rejection.

As stated in the previous response, mailed December 12, 2008, Killion teaches a method of preparing a locking stent. According to Killion, such a locking stent may be made of a medical grade shape memory polymer. Killion further indicates that the locking stent is “preferably made of Nitinol.” Applicants do not contest that shape memory polymers have been described in the art. However, the presently claimed invention provides an assembly comprising a device mounted on an inflatable balloon wherein said device is **substantially resistant to negative recoil** when expanded mechanically to a final predetermined diameter.

The Killion stent, on the other hand, requires “a locking mechanism” that is responsible for maintaining the stent in expanded form, even when made of a medical grade shape memory polymer. See Column 1, lines 55-57, and column 3, lines 31-49 of Killion.

Neither Killion nor Lafont *et al.* disclose or suggest a method as claimed for preparing a polymeric cylindrical **educated** device that is substantially resistant to negative recoil. Such an education requires, in the context of the present invention, the steps of (a) heating the device (which is at a final predetermined radial diameter and wall thickness) to a temperature sufficiently above the glass transition temperature (T_g) of the polymer and for a time sufficient **to erase the memory of previous processing** of the polymeric device, and (b) rapidly cooling the device to a temperature below the T_g of the polymer to quench said device. Applicants

emphasize that it is important for the Examiner to understand that a method to set a shape memory polymer is distinct from a method to educate a shape memory polymer.

As indicated by the Examiner, Lafont *et al.*, contrary to Killion, concretely describe the use of a stent made of a shape memory polymer. It is further noted that, similar to Killion, Lafont *et al.* describe a stent comprising a “catch mechanism [...] for preventing recoil or collapse of the stent following deployment” (see the paragraph linking columns 6-7).

The stent of Lafont *et al.*, as well as the stent of Killion, neither of which have been “educated,” both require the presence of a locking/catch mechanism. In other words, contrary to the material used in the presently claimed device, the material used in the devices of Lafont *et al.* and Killion do not allow them to be substantially resistant to negative recoil in the absence of a lock or catch mechanism. At most, the heating step to a temperature above the glass transition temperature of the polymer used to form the stent, as describe by Lafont *et al.*, is performed “for a time sufficient to render the stent more malleable” (see column 8, lines 20-23 of Lafont *et al.*). However, this is not sufficient to erase the memory of previous processing of the device.

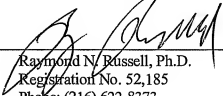
With regard to the cooling step, the Examiner has asserted that the rapidity of the cooling process is not claimed. Applicants respectfully disagree. The claims specifically recite “rapidly cooling the device at a temperature below the Tg of the polymer to quench said device.” As explained by Dr. Sharkawi in the attached declaration, one skilled in the art would clearly understand the meaning of the expression “to quench” as indicating a rapid, forced cooling. Neither Killion nor Lafont *et al.* refer to quenching their respective devices.

The general condition of the pending claims being neither disclosed nor suggested in the prior art for the reasons provided above and within the attached declaration, routine experimentation would have been insufficient guidance for providing a method for preparing a device exhibiting the properties claimed for the present invention. Accordingly, for at least the reasons provided herein, Killion and Lafont *et al.*, either alone or combined, do not render any of the claims in the instant application obvious, and Applicants respectfully request that the rejection of the claims under 35 U.S.C. §103(a) be withdrawn.

Application Number: 10/508,739
Amendment Dated: June 26, 2009
Response to Office Action dated March 26, 2009

Applicants submit that claims 1, 3-10, 19-23 and 27-36 are in condition for allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the claims, he is encouraged to contact the undersigned at the phone number listed below.

Date: 6/25/09

Respectfully submitted,
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Enclosures:
Declaration of Dr. Sharkawi under 37 CFR §1.132
Reference 1: Principles of Polymerization, 4th Ed.